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(54) Title: **CARIES RISK TEST FOR PREDICTING AND ASSESSING THE RISK OF DISEASE**

(57) Abstract: Provided are methods, test devices, and diagnostic kits for predicting, assessing, and diagnosing the risk of a disease using salivary analysis. The method comprises providing a whole (unfractionated) saliva sample from a subject; contacting an aliquot of said saliva with one or more lectins under conditions that allow said one or more lectins to bind to a lectin-binding component of said saliva; detecting the amount of bound lectin; and comparing the amount of bound lectin to the amount known to bind a saliva sample from a control patient, to predict the risk of a disease in the subject. Also provided are methods for reducing the risk of a disease and a method for assessing the risk of the disease at a defined level.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/10169

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; G01N 33/00, 33/53, 33/558;

US CL : 435/6, 7.1; 436/514, 518;

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6, 7.1; 436/514, 518;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	STEINFELD et al., "Labeled Neoglycoproteins and Human Lectins as Diagnostic and Potential Functional Markers in Salivary Glands of Patients with Sjogren's Syndrome." The Journal of Rheumatology, 2000, Vol.27, pages 1910-1916. Abstract Only, see entire document.	1, 3, 4, 5, 9, 26, and 31
Y		2, 6-8, 10-25, 27-30, and 31-60
Y	BELCE et al., "Evaluation of salivary sialic acid level and Cu-Zn superoxide dismutase activity in type 1 diabetes mellitus." Tohoku Journal of Experimental Medicine, November 2000, Vol.192, No.3, pages 215-225. Abstract Only. See entire document.	2
Y	ASTOR et al., "Xerostomia: A prevalent condition in the elderly.", ENT-Ear, Noe, & Throat Journal, July 1999, pages 476-479., See entire document.	10-13 and 27-30
Y	NIELSEN et al., "Differential Expression of Human High-molecular weight Salivary Mucin (MG1) and Low-molecular weight Salivary mucin (MG2)." Journal of Dental Research, November 1996, Vol.75, No.11, pages 1820-1826, See entire document.	14-17 and 20
Y	US 5,585,241 A (LINDMO) 17 December 1996, see entire document.	18-19 and 21-26

☒ Further documents are listed in the continuation of Box C.



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* Special categories of cited documents:

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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document member of the same patent family

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INTERNATIONAL SEARCH REPORT

International application No.
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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,436,721 B (KUO et al.) 20 August 2002, See entire document.	31-60

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/10169

Continuation of B. FIELDS SEARCHED Item 3:
East and West patent database search.
STN- biosis, caplus, embase, medline, cancerlit, japio